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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|-------------|----------------------|---------------------|------------------|
| 09/897,898 | 07/05/2001 | Harm M. Deckers | 034547-0104 | 3117 |
| 22428 | 7590 | 11/30/2004 | EXAMINER | |
| FOLEY AND LARDNER | | | PAK, YONG D | |
| SUITE 500 | | | ART UNIT | PAPER NUMBER |
| 3000 K STREET NW | | | 1652 | |
| WASHINGTON, DC 20007 | | | | |

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/897,898 | DECKERS ET AL. |
| | Examiner | Art Unit |
| | Yong D Pak | 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 October 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14-18 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 14-18 and 29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>see attached</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This application is a CIP of 09/577,147, now issued as U.S. Patent No. 6,372,234.

The after final amendment filed on October 14, 2004 has been entered.

Claims 14-18 and 29 are pending.

Response to Arguments

In view of the amendment filed on October 14, 2004, finality of the previous office action has been withdrawn. A new non-final rejection is set forth below.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn

Priority

As previously stated, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

The parent application, 09/577,147, does not disclose a method of preparing an emulsion formulation comprising a thioredoxin or thioredoxin reductase, which is claimed in the instant application.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on February 6, 2004 and April 19, 2002 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 14 is objected to because of the following informalities: it appears that a conjunction linking clauses (a) through (e) is missing. A conjunction linking clauses (1) through (3) is missing. A conjunction linking clauses (i) through (ii) is missing. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “emulsion chemically reduces a target” is unclear. An emulsion does not have any functional activities. Rather, molecules suspended in the emulsion might have functional activities. The phrase “chemically reduces a target” is unclear. Reduction of a molecule normally involves some type of chemical reaction. Therefore, it is not clear how to differentiate an agent that reduces a target and another agent that chemically reduces a target.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-16, 18 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney et al., Wieles et al. and Voultoury et al.

Claims 14-16 and 18 are drawn to a method of making an emulsion comprising a chimeric polynucleotide comprising a polynucleotide capable of regulating transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from plant and a thioredoxin or thioredoxin reductase which is further linked to a polynucleotide capable of terminating transcription in a plant cell, wherein oil bodies comprising the fusion protein is isolated. Claim 29 limits claim 14 in that the thioredoxin or thioredoxin reductase of the emulsion reduces a target.

Moloney et al. (WO 93/21320 – form PTO-892) teach method of making a chimeric polynucleotide comprising a polynucleotide capable of regulating transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an

oleosin obtained from plant and a heterologous protein of interest which is further linked to a polynucleotide capable of terminating transcription in a plant cell, wherein oil bodies comprising the fusion protein is isolated (pages 2, 8-9, 20, 21 and 26). Moloney et al. also teaches that the fusion protein can be contacted with a substrate of the heterologous protein, leaving out extra steps such as a cleavage and purification step (page 21). Moloney et al. also teaches that oleosins provide a means for separation of foreign proteins from plant derived materials (page 2).

The difference between the reference of et al. and the instant invention is that the reference of Moloney et al. does not teach a method of emulsifying the fusion protein comprising a thioredoxin or thioredoxin reductase.

Wieles et al. (form PTO-892) teaches polynucleotides encoding a thioredoxin and thioredoxin reductase (abstract and pages 921-922). Wieles et al. also teaches that thioredoxin and thioredoxin reductase is involved in redox regulation (abstract). Thioredoxin and thioredoxin reductase are well established proteins in the art (see NiceZyme: EC 1.8.1.9 – form PTO-892).

Voultoury et al. (EP 0 680 751 A1 – form PTO-892) teach a method of formulating emulsions comprising oil body proteins (pages 2-5 and see corresponding U.S. Patent No. 5,683,740 – PTO-1449 – for translation into English). Voultoury et al. teaches that emulsions can be used in a variety of applications, such as in pharmaceutical compositions.

Combining the teachings of Moloney et al., Wieles et al. and Vouloutry, it would have been obvious to one having ordinary skill in the art use thioredoxin or thioredoxin reductase of Wieles et al. in the fusion protein of taught by Moloney et al. and formulate the fusion protein into an emulsion. One of ordinary skill in the art would have been motivated to use thioredoxin or thioredoxin reductase as the heterologous protein in the fusion protein of Moloney et al. since thioredoxin and thioredoxin reductases play important roles in redox regulation. One of ordinary skill in the art would have had a reasonable expectation of success of making the fusion protein and isolating the fusion protein since Monoley et al. teaches fusion proteins comprising oleosins can be successfully separated from plant derived materials. One of ordinary skill in the art would have been motivated to formulate a fusion protein comprising an oil body protein and a thioredoxin or thioredoxin reductase to stabilize the thioredoxin or thioredoxin reductase in order to use it to reduce their substrates without adding steps in cleaving the oleosin from thioredoxin or thioredoxin reductase. One of ordinary skill in the art would have had a reasonable expectation of success in making the emulsion since Voultoury et al. successfully teaches an emulsion comprising oleosins.

Therefore, the above references render claims 14-16, 18 and 29 prima facie obvious to one of ordinary skill in the art.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney et al., Wieles et al. and Voultoury et al. as applied to claims 14-16, 18 and 29 above, and further in view of Hildebrand et al.

Claim 17 is drawn to a method making an emulsion comprising a fusion protein, wherein the fusion protein is expressed in safflower cells.

The references of Moloney et al., Wieles et al. and Voultoury et al.in combination teach a method of making an emulsion comprising a fusion protein comprising a thioreodixn or thioredoxin reductase and an oleosin, as discussed above.

The difference between the combined references and the instant invention is that the combined references do not teach the method using a safflower cell for the expression of the fusion protein.

Hildebrand et al. (EP 0 550 162 A1 – form PTO-892) teach a method of expressing heterologous proteins in safflower cells (page 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to express the fusion protein in safflower cells. The motivation of expressing the fusion protein in safflower cells is to express the oil body protein in an oil-bearing crop. One of ordinary skill in the art would have had a reasonable expectation of success since expression of fusion proteins in plant cells such as safflower cells are performed routinely in the art.

Therefore, the above references render claim 17 is prima facie obvious to one of ordinary skill in the art.

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECH 1652, ROOM 1600